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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/935,550	08/24/2001	Robert Naylor Laurie	P07351US00/LRP	8711

881 7590 08/27/2002
LARSON & TAYLOR, PLC
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SUITE 900
ALEXANDRIA, VA 22314

EXAMINER

SHEIKH, HUMERA N

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 08/27/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/935,550	LAURIE ET AL.	
	Examiner	Art Unit	
	Humera N Sheikh	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 25 June 2002.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1 and 3-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1 and 3-12 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Application

Acknowledgement is made of the receipt of the Amendment filed 06/25/02.

Claims 1 and 3-12 are pending. Claims 1 and 3-12 remain rejected. Claim 2 has been cancelled as requested. The previous 35 USC 112, second paragraph rejections have been withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 8 and 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "any other suitable mineral" in claims 8 and 11 is a relative term, which renders the claim indefinite. The term "any other suitable mineral" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The term is indefinite because it does not provide a reference point or state with clarity, as to which specific mineral, aside from the EDTA and

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selenium selenite, is being comprised in the formulation. Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1 and 3-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Howard (US Pat. No. 4, 335,116).

Howard teaches a method for preparing stable trace element solutions for parenteral administration to livestock animals comprising the use of at least two organic water-soluble metal-ion-complexing agents, EDTA and glycine (see entire reference).

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The metal compounds taught are zinc, copper, manganese, chromium and selenium. The instantly claimed invention pertains to a method of preparing a trace element solution, providing a mixture of an EDTA-complex with a sodium selenite solution. The prior art discloses such a method for preparing mineral, nutritive supplement solutions wherein salts of zinc, copper, manganese and chromium are complexed with ethylenedinitrilotetraacetic acid (EDTA) and admixed with a selenium glycine complex. The only difference between the prior art and the instant claims is that the prior art teaches complex solutions that are made individually and may require more time in processing the formulation. There is ample motivation provided by the prior art to use EDTA with a selenium solution to help maintain and restore mineral deficiencies in animals, particularly livestock. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the method of Howard, who teaches an EDTA-selenium complex, with the expected result of obtaining a suitable trace element solution effective for maintaining and restoring normal growth and development in livestock animals.

Response to Arguments

Applicant's arguments filed 06/25/02 have been fully considered but they are not persuasive. The Applicant argued, "Claims 1 and 3-12 are not anticipated or made obvious by the Howard patent." The Applicant specifically addressed issues regarding desired higher concentrations achievable by the presently claimed invention, stating,

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"The higher concentrations are essential to produce an injection having a manageable volume and that the process according to the present claims enables the manufacture of a product comprising high concentrations". These arguments are not found to be persuasive. The instantly claimed invention is drawn to a method of preparing a trace element solution, comprising the steps of a) preparing more than one EDTA-complex as a sodium salt, b) providing a sodium selenite solution and c) combining the EDTA-complexes and the sodium selenite solution. The Examiner points out that Howard teaches a similar method of preparing a trace element solution and providing a mixture of an EDTA-complex with a sodium selenite solution. The prior art explicitly teaches such a method for preparing mineral, nutritive supplement solutions wherein salts of zinc, copper, manganese and chromium are complexed with ethylenedinitrilotetraacetic acid (EDTA) and admixed with a selenium glycine complex. Furthermore, these arguments are not persuasive since the Applicant has not claimed properties and/or units relating to specific concentration requirements.

The Applicant argued, "the method of Howard requires the use of stock solutions, making it extremely cumbrous, tedious and unfit for mass production, especially where solutions of variable composition and concentration are concerned." This argument is not found to be persuasive since Howard teaches a method for preparing stable trace element solutions comprising the same ingredients as instantly claimed (a mixture of an EDTA-complex with a sodium selenite solution), which would therefore result in the same properties and results as those desired by the applicant. In addition, specific

properties and/or units have not been claimed, but rather a method of preparing, which has been met by the prior art.

The Applicant argued, "Howard is not capable of producing a product free of unacceptable contaminants." This argument is not persuasive because Howard does in fact teach an effective method for preparing stable trace element solutions, regardless of the addition of sodium or sodium chloride.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera Sheikh whose telephone number is (703) 308-4429. The examiner can normally be reached on Monday through Friday from 7:00A.M. to 4:30P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.


THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
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